

REMARKS

I. Objection to Claims 1, 4, 5 and 11

The March 31, 2006 Office Action objected to claims 1, 4, 5 and 11 due to specific references to antibiotics which recommended amendment to antibiotic instead. As recommended, claim 1 line 4 has been revised, as well as claim 5 line 2 and claim 11 line 4. Claim 4 has been canceled. Since Applicants have adopted the amendment as suggested by the Examiner, Applicants respectfully request that the objection to the claims be withdrawn.

II. Rejection of Claims Under 35 U.S.C. §112 First Paragraph

The Office Action stated that claims 1-4, 6 and 8 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. According to the Office Action, claim 1 is drawn to a vector for the surface expression of antibiotics comprising one or more of pgsB, pgsC, and pgsA and any gene encoding any amphiphilic antibiotic with antibacterial, antifungal and anticancer activities. Dependent claim 4 recites that the amphiphilic peptide antibiotic "has an identity with" the peptide P5, which is interpreted to mean any amphiphilic peptide with at least one amino acid in common with the peptide P5.

The claims as amended now recite specific genetic sequences, in response to the Examiner's belief that the reference in claim 1 to 'a gene encoding an amphiphilic peptide antibiotic' would be overly broad. Claim 1 is now specifically drawn to an expression vector with the P5 gene, by reciting "a gene encoding P5 an amphiphilic peptide antibiotics with antibacterial, antifungal and anticancer activities, wherein P5 peptide is encoded by the base sequence of SEQ ID NO: 4." The perceived ambiguity upon which the rejection under 35 U.S.C. 112, first paragraph was based, has been overcome with the specific recitation of the P5 gene and cancellation of claim 4. Applicants respectfully request that the rejection of claims 1-4, 6 and 8 be withdrawn.

The Office Action also stated that claims 5, 7 and 9 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action stated that the application discloses "*E. coli* DCTC 10350BP (sic) and plasmid pHCE1LB:pgsA-P5 that is encompassed by the definitions for biological material set forth in 37 C.F.R. § 1.801." Please note, the Office Action has misstated the accession

number from the application. The correct accession number is KCTC 10350BP, which is recited at paragraph 55 of the application. The "DCTC 10350BP" accession number referenced in the Office Action is not mentioned in the application, whereas KCTC 10350BP is and will be the accession number used in responding to the Office Action.

The Office Action also stated that biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. The Office Action contended that if this biological material is not obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the biological material and the specification must contain reference to the deposit, including deposit number, date of deposit, name and address of the depository, and the complete taxonomic description. Applicants respectfully assert that paragraph 55 of the application specifically identified the biological deposit related to the claims at issue. Applicants have further amended the specifications to provide related detail about the biological deposit of *Escherichia coli* JM109/pHCE1LB:pgsA-P5 with accession number KCTC 10350BP previously identified in paragraph 55 of the application as filed and hereby provides a copy of the deposit receipt for the same. Applicants believe that the deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. In light of the deposit receipt provided and the additional clarification of paragraph 55 as amended, Applicants believe that they have fully complied with the enablement requirement and respectfully request that the rejection of claims 5, 7 and 9 be withdrawn.

Notwithstanding the aforementioned, Applicants also provide the following considerations. The construction of pHCE1LB:pgsA-P5 is prepared by inserting the pgsA gene of cellular outer membrane genes (pgsBCA) involved in synthesis of poly-gamma-glutamate derived from *Bacillus subtilis* var. *chungkookjang* (KCTC 0697BP) into pHCE1LB (pHCE1LB is known and available to public) as shown in Example 1 to insert P5 gene which is obtained from nucleotides of SEQ ID Number 4 and SEQ ID Number 5 into the recombinant vector. Therefore, those who are skilled in the art can readily and reproducibly construct the recombinant vector by inserting the gene into pHCE1LB, which is known and available to the public by using restriction enzymes. Also, a copy is hereby provided of the deposit receipt of *E. coli* KCTC 10350BP which is transformed with the recombinant vector.

So, those skilled in the art are able to obtain the recombinant vector readily by culturing and isolating it from the transformed *E. coli* KCTC 10350BP. Based on the provided amendments, remarks and copy of the microorganism deposit receipt, the written description requirement has been satisfied for claims 1-4, 6 and 8 and the enablement requirement has been addressed for claims 5, 7 and 9. Consequently, Applicants respectfully request that the rejection of the claims under 35 U.S.C. §112, first paragraph, be withdrawn and the claims be permitted to pass to allowance.

III. Claim Rejections Under 35 U.S.C. §103(a)

The Office Action stated that claims 1-9, 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sung et al. (WO 03/014360) in view of “[amphiphilic peptide antibiotic gene].” According to the Office Action, Sung et al. disclose vectors for the surface expression of target proteins of interest, comprising one or more than two genes selected from the group consisting of pgsB, pgsC and pgsA, said genes encoding a poly-gamma-glutamate synthetase complex. The pHCE1LB vector containing a foreign gene of interest is also disclosed. However, the present invention as claimed relates to the surface expression vector comprising the gene encoding the P5 peptide. Since it is not disclosed nor implied in Sung et al., those who are skilled in the art cannot readily construct the claimed inventive vector from Sung et al.

Also, while amphiphilic peptide antibiotics having anti-bacterial, anti-fungal and anticancer activity are disclosed by Boman et al., Boman et al. only disclose that cecropin A and melitin as members of amphiphilic peptides having antibiotic activity, not the P5 peptide recited. As disclosed in the present application, many studies on the antibiotic activities of amphiphilic peptides such as cecropin A and melitin were conducted (See page 2 lines 15-28). Thus, the surface expression vector encoding P5 peptide having antibacterial, antifungal and anticancer activities cannot be derived from the above Sung and Boman. The only basis asserted by the Examiner for combining the Boman reference with Sung “since Boman et al. discloses the usefulness of said amphiphilic peptides” based on “the benefits disclosed by Sung et al.” However, the basic “usefulness” of Boman does not show or even suggest any basis for combining it with Sung in light of Sung’s general “benefits” disclosed. Moreover, Boman does not teach the introduction of the gene encoding for the P5 peptide, and as such does not show or suggest to

one skilled in the art the present invention as claimed. Consequently, in light of the amended claims as provided, Applicants respectfully request that the rejection under 35 U.S.C. §103 be withdrawn and the claims be permitted to proceed to allowance.

CONCLUSION

Applicants respectfully submit that claims 1-3, 5-8, 11 and 12 are believed to be in allowable form and requests that they be allowed. Therefore, favorable consideration of the foregoing election, amendment and these remarks are kindly requested. The Examiner is cordially invited to telephone the undersigned for any reason which would advance herein elected method claims to allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. David LaRiviere', with a long horizontal flourish extending to the right.

F. David LaRiviere
Reg. No. 27,207

FDL/JCS/taa
July 28, 2006
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INTERNATIONAL FORM

issued pursuant to Rule 7.1

1. IDENTIFICATION OF THE MICROORGANISM

Escherichia coli
JM109/pECE1LB:pgsA-P5

Accession number given by the
INTERNATIONAL DEPOSITARY
AUTHORITY:

KCTC 10350BP

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

[x] a scientific description
[] a proposed taxonomic designation
(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above, which was received by it on October 04 2002.

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International Depositary Authority on _____ and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on _____

V. INTERNATIONAL DEPOSITARY AUTHORITY

Address: Korea Research Institute of
Bioscience and Biotechnology
(KRIBB)
#52, Oun-dong, Yusong-ku,
Taejon 305-333,
Republic of Korea

Signature(s) of person(s) having the power
to represent the International Depositary
Authority of authorized official(s):

PARK Yong-Ha, Director
Date: October 09 2002